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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,749	05/31/2005	Jorge Setoain Quinquer	ABG 3002	1639

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	

NOTIFICATION DATE	DELIVERY MODE
02/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/534,749	QUINQUER ET AL.	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/5/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-4,6,7,9,10 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,8 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 10/5/09 wherein claims 5 and 11 were amended.

Note: Claims 1-17 are pending.

WITHDRAWN CLAIMS

2. Claims 1-4, 6, 7, 9, 10, and 12-17 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

3. The Applicant's arguments and/or amendment filed 10/5/09 to the rejection of claims 5, 8, and 11 made by the Examiner under 35 USC 102, 103, and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 First Paragraph Rejection

The 112 first paragraph rejection is WITHDRAWN because Applicant amended the claims to overcome the rejection.

112 Second Paragraph Rejections

The 112 second paragraph rejection is WITHDRAWN because Applicant amended the claims to overcome the rejections.

102 Rejection

The 102 rejection is WITHDRAWN because Applicant amended the rejection to overcome the rejection.

103 Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 5, 8, and 11 under 35 U.S.C. 103(a) as being unpatentable over Lamberg et al (Nuklearmedizin, 1967, Vol. 6, No. 1, pp. 16-19) in

view of Wilbur et al (US Patent No. 4,885,153) or in view of Baldwin et al (US Patent No. 4,279,887) is MAINTAINED.

Applicant's Assertions

In summary, Applicant asserts that (1) the claims have been amended to exclude the presence of 125I as a radioisotope; (2) the primary reference does not disclose or suggest a pharmaceutical composition for detection of amyloid plaques in the central nervous system; (3) the primary reference does not suggest or disclose a composition having any utility in the central nervous system; (4) the primary reference fails to disclose other possible isotopes of iodine that may be used with the structure; and (5) the primary reference only uses 125-iodine in laboratory rat research, not in the testing of a pharmaceutical. In addition, it is asserted that (6) Wilbur et al do not list 125-iodine as a preferred radiohalogen, but list other possible radioisotopes. (7) The replacement of I-125 and I-123 would not be obvious because the isotopes have different half-lives which render them suitable for different purposes.

Examiner's Response

Applicant's arguments are non-persuasive for the following reasons. First, it is noted that **Lamberg et al** disclose 125I-labeled iodochloroxyquinoline which has the structure (the iodine is radioactive, 125-iodine) [see entire document, especially, page 16, first paragraph). The labeled iodochloroxyquinoline fulfills the requirement of the instant invention when Y = hydrogen; X = oxygen; A = nitrogen; m = 1; n = 1; p = 1; B =CR_5; D = CR_6; E = CR_7; R_5 = hydrogen; R_6 = hydrogen; R_7 = hydrogen; R_1 = 125-iodine; R_2 = hydrogen; and R_3 = chlorine. However, while Lamberg et al disclose a

radioactive iodochloroxyquinoline compound, the reference fails to disclose other possible isotopes of iodine that may be used with the instant invention.

Wilbur et al disclose radiohalogenated proteins (see entire document, especially, abstract). In particular, the document is cited because it discloses that it is known in the art to replace any radioisotope of iodine (i.e., 123-iodine, 125-iodine, or 131-iodine) with another (column 3, lines 43-53).

Baldwin et al disclose agents useful for imaging (see entire document, especially, abstract). In particular, Baldwin et al is cited for its teaching that it is known in the art to replace any radioisotope of iodine (i.e., 123-iodine, 125-iodine, or 131-iodine) with another (column 2, lines 64-67).

As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lamberg et al using the teachings of Wilbur et al and Baldwin et al and replace the 125-iodine substituent with 123-iodine because the cited secondary references each disclose that 125-iodine and 123-iodine may be used interchangeably. Thus, replacing one iodine substituent with another is within the skill of a skilled artisan. Furthermore, since each of the secondary documents discloses that 125-iodine and 123-iodine are interchangeable, a skilled artisan would be motivated to interchange one isotope for the other depending on the desired imaging being conducted.

While the claims have been amended to exclude the presence of 125I as a radioisotope, one would still be motivated to use other isotopes besides 125-iodine because in the background of Baldwin et al (column 1, lines 5-7), it is disclosed that the

use of radioiodine to label organic compounds for use in diagnostic medicine is well documented in the literature. Furthermore, in column 2, lines, 64-66, it is disclosed that all radioisotopes of iodine (i.e., I-123, I-125, and I-131) may be used to radiolabel aryl groups with iodine attached thereto. Also, Wilbur et al disclose that their invention is directed to radiohalogenated small molecules (i.e., haloaryl compounds) that may be used for *diagnosis* and *therapy* (see abstract and column 1, lines 12-16). In the background of Wilbur et al (column 1, lines 26-28), it is disclosed that radionuclides of halogens possess properties that make them very attractive for both diagnostic imaging and therapy. Then, Wilbur et al goes on to disclose various isotopes (radioiodine, bromine, fluorine, etc.) and their various half-lives and modes of imaging. Hence, the skilled artisan would recognize that the isotopes used for diagnosis are not necessarily the same as those used for therapy. Therefore, one would not expect all the isotopes to have the same half-lives since the selection of isotopes depends upon for what purpose the compound/composition is being used (i.e., positron imaging, radiotherapy, etc.). Furthermore, Applicant is reminded that a reference is not limited to its preferred embodiments, but must be considered for what it teaches as a whole.

In regards to Applicant's assertion that the reference(s) does/do not disclose or suggest a pharmaceutical composition for detection of amyloid plaques in the central nervous system, Applicant is reminded that the instant invention is directed to a product (compound and composition), not a method of use. While the product claims disclose the intended use of the product, Applicant is reminded that according to MPEP 2111.02, Section II, if the body of a claim fully and intrinsically sets forth all of the limitations of

the claimed invention, and the preamble merely states the purpose or intended use of the invention, rather than any distinction definition of any of the claimed invention's limitation, then the preamble is not considered a limitation and is of no significance to claim construction. In this particular case, the body of the claim fully and intrinsically sets forth all of the limitations (components) necessary for the compound. Furthermore, Applicant is reminded that according to MPEP 2112.01, Section II, chemical compositions/compounds are inseparable from their properties. As a result, if the prior art teaches the chemical structure, then properties associated with Applicant's product are also associated with the products of the prior art (*In re Spada*, 911, F. 2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990).

In response to Applicant's assertion that the primary reference only uses 125-iodine in laboratory rat research, not in the testing of a pharmaceutical. The claims are directed to a product, thus, it is not necessary that the prior art disclose using the product under various condition, only that it, like Applicant, discloses the product.

NEW GROUNDS OF REJECTIONS

New Matter Rejection

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 5, 8, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claims contain new matter. Specifically, in independent claim 5, line 27, the phrase '(CH2)s-CO-R', wherein s is 1, 2, or 3' has been added. The phrase is new matter because the originally filed claims and the specification both disclose the use of the variable 'r' instead of 's' in the formula. Applicant is reminded that one cannot arbitrarily change variables in a formula without them being supported in the specification. If Applicant is in disagreement with the Examiner regarding the new matter rejection, it is respectfully requested that Applicant point to page and line number wherein support for the claim may be found.

112 Second Paragraph Rejection

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, line 7, should 'cardohydrate' be 'carbohydrate'? Please make the appropriate correction, if necessary.

COMMENTS/NOTES

8. Once again, it is noted that Applicant's elected group, Group (7), is directed to compounds as set forth in independent claim 5 wherein one of A, B, D, or E is a nitrogen atom. Thus, since A is a nitrogen atom, B, D, and E are carbon atoms. In

addition, since Applicant's elected species is 5-chloro-7-[123I]iodo-8-hydroxyquinoline, the ring containing the A-substituent has six-members. The search has not been extended beyond Applicant's elected species because prior art was found which could be used to reject the claims.

9. Applicant is reminded that any amendments to the claims should be underlined. It is duly noted that in claim 5, line 7, the phrase 'X-Y represents O-H, S-H, =O, or a cardohydrate radical' was insert without any indication that the phrase was added. Review of the pending claims from 5/15/09 indicate that the phrase was not previously added to the claims.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

January 27, 2010